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EXAMINER	
JOHNSON, N	
ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 02/10/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10·26·98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-39 is/are pending in the application.
Of the above, claim(s) 1-9, 17-24, 26-29, 31-34, 36-37 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 10-16, 25, 30, 35, 38-39 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2X (filed 11/16/98 and 5/14/98)
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Applicant's election of Group II, claims 10-16, 25, 30, 35 and 38-39 in Paper No. 14, filed 10/26/98 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-39 are pending.

Claims 1-9, 17-24, 26-29, 31-34, 36-37, drawn to non-elected inventions, are withdrawn.

Claims 10-16, 25, 30, 35 and 38-39 are examined on the merits.

3. The drawings are objected to for the reasons indicated on the enclosed PTO-948. Correction is required.

4. Claims 38 and 39 are rejected under 35 U.S.C. § 101 because the claim is directed to non-statutory matter. The "gene," as claimed, absent limitation to "an isolated" or "purified" product, has the same characteristics as a gene *in situ* in a human being and therefore does not constitute patentable subject matter. In the absence of the hand of man the naturally occurring gene is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

5. Claims 10-16, 25, 30, 35 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in the recitation "having." It is unclear if this recitation is closed (consisting of) or open (comprising) language. For examination purposes, the recitation having is interpreted to be open language.

The recitations "CS141 polynucleotide" (claim 10), "CS141 gene" (claim 11), "CS141 epitope" (claims 14,25, 30), "CS141" (claim 15) and "CS141 protein" (claim 38) are vague and indefinite. The recitation "CS141" is a laboratory designation. Absent limitations setting forth

identifiable structural or functional characteristics, the identity of the CS141 polynucleotide, CS141 gene, CS141 epitope and CS141 protein are unknown to one of skill in the art.

The recitation "derived from" in claims 11 and 15 is vague and indefinite. The specific derivation processes encompassed by the claims is unclear.

The recitation "hybridizing to" in claim 11 is vague and indefinite. Absent specific hybridization conditions, the metes and bounds of the claimed polynucleotides are unclear.

The recitation "is produced by recombinant techniques" in claim 12 is vague and indefinite. Likewise, the recitation "is produced by synthetic techniques" in claim 13 is vague and indefinite. It is unclear how the two different production methods modify the claimed polynucleotide.

The recitation "% identity" in claims 10, 11, 15, 25, 38 and 39 is vague and indefinite. This language indefinite in the absence of a teaching in the specification of the percentage algorithm to use and the parameters to set in the algorithm. Accordingly, claims using language of % sequence identity are indefinite unless the disclosure includes an explanation of how the calculation is made. This usually requires an algorithm and the parameters (e.g. gap penalties, mismatch penalties) to set. A table or figure exemplifying a sequence alignment and the numerical % sequence identity, without more elaboration, does not satisfy the need for explicit instructions on how to interpret the claim, because it is not possible to work backward from the example to derive the algorithm and parameters used.

Claims 14, 25, 30 are vague and indefinite in the recitation "at least one CS141 epitope." It is unclear what structural feature characterizes an epitope.

Claim 30 is vague and indefinite in the recitation "and fragments and complements thereof." Is the claim drawn to fragments and complements of the claimed transfected cell or to cells transfected with fragments or complements of a nucleic acid selected from the group consisting of SEQ ID NO:1-13?

6. Claims 11-16 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 11-14 are drawn to polynucleotides "derived from a CS141 gene," claims 15-16 are drawn to "a nucleic acid sequence that includes an open reading frame derived from CS141," claim 38 is drawn to "a gene ... which codes for a CS141 protein," and claim 39 is drawn to "a gene ... comprising DNA having at least 50% identity with SEQ ID NO:12 or SEQ ID NO:13." Thus, all cited claims are broadly drawn to a "CS141 gene." The specification describes only the various overlapping cDNA sequences SEQ ID NO:1-13. The specification does not describe any of the structural elements of a gene that would encode these various cDNA sequences. For example, the specification does not describe the organization, location or actual DNA sequences of promotor and regulatory regions and introns, all defining elements of a "gene." Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the interim guidelines concerning compliance with the written description requirement of 35 USC 112, first paragraph published in the Official Gazette (1214 OG18-1835), also available at www.uspto.gov.

7. Claims 10-16, 25, 30, 35 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 10 is drawn to a "CS141 polynucleotide," claims 11-14 are drawn to a "CS141 gene," claim 15 is drawn to "an open reading frame derived from CS141," claims 14, 25 and 20 are drawn to epitopes of "CS141" and claim 38 is drawn to a "CS141 protein." The specification teaches only the various overlapping cDNA sequence of SEQ ID NO:1-13 and the amino acid sequence encoded by these polynucleotide sequences (SEQ ID NO:24-28). Absent additional guidance (structural and/or functional) one of skill in the art can not predictably make and use the

broadly claimed CS141 polynucleotide, CS141 gene, CS141 protein or open reading frame derived from CS141 without undue experimentation.

Claims 11, 38 and 39 are broadly drawn to a "gene." The specification teaches only various overlapping cDNA sequence. A "gene" is art known to have a characteristic genomic structural organization, in addition to the given mRNA (cDNA) sequence that it might encode, such as the organization, location and actual DNA sequences of promotor and regulatory regions and introns. Absent teachings in the specification characterizing this structural organization of the claimed gene, one of skill in the art can not make and use the claimed gene, with a reasonable expectation of success and without undue experimentation.

Claims 14, 25, 30 are broadly drawn to "at least one CS141 epitope." Given the uncertainty of what constitutes and epitope (discussed in paragraph 4, above, one of skill in the art can not predictably make and use the claimed CS141 epitope.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by p.167 of the 1994-1995 Promega catalog. Page 167 discloses bulk dNTP's, which are the same as the claimed "fragments ... thereof" of claims 11-13. Claims 12 and 13 are drafted in the product-by-process format. The references do not describe the production of the claimed polynucleotide using methods identical to that recited; "by recombinant techniques" in claim 12 or "by synthetic methods" in claim 13. However, the recitation of a process limitation in claims 12 and 13 is not viewed as positively limiting the claimed product absent a showing that the recited process of making imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is upon the applicants to establish a patentable distinction between the claimed and referenced products.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over p.167 of the 1994-1995 Promega catalog. The teachings of p. 167 of the Promega catalog, of fragments of a polynucleotide sequence, have been discussed in the above paragraph. The Promega catalog does not teach "a test kit ... comprising a container containing" said polynucleotide sequences. However, test kits containing said containers would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the teachings of the

Promega catalog, that the polynucleotide fragments are supplied at a concentration of 100mM in water.

12. Claims 11-16, 25, 30 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,733,748 (filed June 6, 1995). U.S. Patent No. 5,733,748 (the '748 patent) discloses a polynucleotides, recombinant expression system comprising said polynucleotide sequence and recombinant methods of producing a polypeptide product from said polynucleotide sequence and "gene fragments" that are the same as that claimed. The '748 patent discloses polynucleotides comprising a polynucleotide sequence that is 100% identical, for example to the claimed SEQ ID NO:7, SEQ ID NO:8, 54.9% identical overall to SEQ ID NO:12 (by MPSRCH parameters) and encode an amino acid sequence that is 100% identical to SEQ ID NO:26-28. Please see copies of relevant portions of sequence search results.

13. Claims 10 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,733,748 (filed June 6, 1995). The teachings of the '748 patent, of a polynucleotide sequence "having at least 50% identity to" SEQ ID NO:7, has been discussed in the above paragraph. The '748 patent does not teach "a test kit ... comprising a container containing" said polynuceotide sequence (claim 10) or said test kit "further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups" (claim 35). However, test kits containing said containers and tools would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the teachings of the '748 patent on the use of said polynucleotides in diagnostic assays, including hybridization assays of human samples including blood, urine, saliva and tissue biopsy material (see col.7, line 67- col.8, line 56).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner

can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A. Johnson, Ph.D.
Patent Examiner, Group 1642
February 9, 1999